

#12  
Amend + A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Heather J. JORDAN

Appl. No. 09/613,903

Filed: July 11, 2000

For: **Nucleic Acid Ladders**



Confirmation Number: 1446

Art Unit: 1634

Examiner: Sisson, B

Atty. Docket: 0942.44500001/RWE/B-C

**Amendment And Reply Under 37 C.F.R. § 1.111**

**RECEIVED**

Commissioner for Patents  
Washington, D.C. 20231

MAY 10 2002

Sir:

**TECH CENTER 1600/2900**

In reply to the Office Action dated **February 12, 2002** issued in the above-referenced patent application, Applicant submits the following Amendment and Remarks. This Amendment is provided in the following format:

- (A) A clean version of each replacement paragraph/section/claim along with clear instructions for entry;
- (B) Starting on a separate page, appropriate remarks and arguments. 37 C.F.R. § 1.121 and MPEP 714; and
- (C) Starting on a separate page, a marked-up version entitled: "Version with markings to show changes made."

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a),

and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 19-0036.

***Amendments***

***In the specification:***

After the title and inventor's name and before the introduction, please insert the following new paragraph:

---

**Cross-Reference to Related Applications**

a<sup>1</sup> This application claims priority to application serial number 08/892,884, filed July 15, 1997, now abandoned, the entire specification of which is specifically incorporated herein by reference.

---

***In the Claims:***

Please cancel claims 1-42 without prejudice or disclaimer.

Please add the following new claims:

---

a<sub>2</sub> 43. (New) A composition comprising a plurality of double-stranded DNA fragments of different lengths, wherein fragments of each length are present in an amount that produces bands of substantially equal intensity after the composition is separated by gel electrophoresis and stained with a detectable label.

44. (New) A composition according to claim 43, wherein fragments of each length are present in a substantially equal relative mass.

45. (New) A composition according to claim 44, wherein the relative mass of fragments of a first length is no more than 2.5 times the relative mass of fragments of any other second length.

46. (New) A composition according to claim 44, wherein the relative mass of fragments of a first length is no more than 1.5 times the relative mass of fragments of any other second length.

47. (New) A composition according to claim 43, wherein said fragments range in length from about 25 kb to about 100 bases.

48. (New) A composition according to claim 43, wherein said fragments range in length from about 20 kb to about 100 bases.

49. (New) A composition according to claim 43, wherein said fragments range in length from about 12 kb to about 100 bases.

50. (New) A composition according to claim 43, wherein said fragments are of lengths selected from the group of nucleic acid fragment lengths consisting of about 12,000 basepairs, about 11,000 basepairs, about 10,000 basepairs, about 9,000 basepairs, about 8,000 basepairs,

about 7,000 basepairs, about 6,000 basepairs, about 5,000 basepairs, about 4,000 basepairs, about 3,000 basepairs, about 2,000 basepairs, about 1,650 basepairs, about 1,000 basepairs, about 850 basepairs, about 650 basepairs, about 500 basepairs, about 400 basepairs, about 300 basepairs, about 200 basepairs, and about 100 basepairs.

51. (New) A composition according to claim 43, comprising two or more fragments ranging in length from about 25 kb to 100 basepairs.

92 52. (New) A composition according to claim 43, comprising fragments that differ in length by increments of about 1,000 basepairs.

53. (New) A composition according to claim 43, comprising fragments that differ in length by increments of about 100 base pairs.

54. (New) A composition according to claim 43, comprising both fragments that differ in length by increments of about 1,000 basepairs and fragments that differ in length by increments of 100 basepairs.

55. (New) A composition according to claim 43, wherein the detectable label is ethidium bromide or SYBR green.

56. (New) A composition according to claim 43, further comprising a dye.

57. (New) A composition according to claim 56, wherein the dye is selected from the group consisting of bromophenol blue, xylene green, and mixtures thereof.

58. (New) A composition according to claim 43, further comprising an additional fragment present in an amount that produces a band visibly brighter than the bands of substantially equal intensity.

59. (New) A kit comprising the composition of claim 43.

60. (New) A kit comprising the composition of claim 54.

61. (New) A kit comprising the composition of claim 57.

62. (New) A kit comprising the composition of claim 58.

---

### ***Remarks***

Based on the amendments to claims presented above and the following remarks, Applicant respectfully requests that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn. As a preliminary matter, the specification has been amended to reflect the continuity data on the Official Filing Receipt. This application is a continuation of application serial number 08/892,884, filed July 15, 1997. Accordingly, the effective filing date of this application is July 15, 1997.

#### ***I. Status of the Claims***

Claims 1-42 are canceled by this amendment and new claims 43-62 are presented with claim 43 being the sole independent claim.

#### ***II. Summary of the Office Action***

In the Office Action dated February 12, 2002, the Examiner made one objection and ten rejections of the claims. Applicant respectfully offer the following remarks to overcome the objection and rejections.

#### ***III. Support for the New Claims***

Support for new claim 43 may found throughout the specification, *inter alia*, at page 5, lines 13-20.

Support for new claim 44 may found throughout the specification, *inter alia*, at page 5, lines 13-20.

Support for new claim 45 may found throughout the specification, *inter alia*, at page

9, lines 8-15.

Support for new claim 46 may found throughout the specification, *inter alia*, at page 9, lines 8-15.

Support for new claims 47-49 may found throughout the specification, *inter alia*, at page 5, lines 7-12.

Support for new claim 50 may found throughout the specification, *inter alia*, at page 4, line 28 to page 5, line 12, and in Example 2 at pages 19-20.

Support for new claim 51 may found throughout the specification, *inter alia*, at page 5, lines 7-12.

Support for new claim 52 may found throughout the specification, *inter alia*, at page 4, lines 28-32.

Support for new claim 53 may found throughout the specification, *inter alia*, at page 5, lines 1-2.

Support for new claim 54 may found throughout the specification, *inter alia*, at page 9, line 28 to page 10, line 6 and page 13, line 28 to page 14, line 4.

Support for new claim 55 may found throughout the specification, *inter alia*, at page 15, lines 4-6.

Support for new claims 56 and 57 may found throughout the specification, *inter alia*, at page 16, lines 4-6.

Support for new claim 58 may found throughout the specification, *inter alia*, at page 14, lines 5-13.

Support for new claims 59-62 may found throughout the specification, *inter alia*, at page 15, line 22 to page 16, line 6.

***IV. The Objection to Claims 35-37 is Moot***

Claims 35-37 have been canceled in this amendment. Accordingly, this objection is moot.

***V. The Rejection of Claims 1-27 and 35-37 under 35 U.S.C. § 112 Must be Withdrawn***

Claims 1-27 and 35-37 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claim invention. Insofar as this rejection may be applied to the newly presented claims, Applicant has the following remarks.

The present claims are drawn to a composition comprising double-stranded DNA fragments of different sizes. The specification clearly provides support for the invention as now claimed. With regard to the Examiner's allegation that the upper limit of the size range is 12 kb, Applicant respectfully directs the Examiner's attention to page 5, first full paragraph where ranges having an upper limit greater than 12 kb are discussed. Furthermore, Applicant submits that the Examiner is improperly attempting to limit the present invention to the explicitly recited species. MPEP § 2163.05 reads, in pertinent part:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species

The present specification provides examples of a representative number of species of the presently claimed genus. Accordingly, Applicant respectfully request reconsideration and withdrawal of this rejection as it may be applied to the newly presented claims.



**VI. *The Rejections of Claims 1-27 and 35-37 Under 35 U.S.C. § 112, second paragraph, Must Be Withdrawn***

The Examiner has made seven rejections of the claims under 35 U.S.C. § 112, second paragraph, alleging that the claims are indefinite and/or confusing. Applicant respectfully submits that these rejections have been obviated by the amended claim language and requests reconsideration and withdrawal of these rejections.

**VII. *The Rejection of Claims 1-12, 15, 16, and 21-27 Under 35 U.S.C. § 102(b) As Being Anticipated by the 1997 Novagen Catalog Must Be Withdrawn***

Claims 1-12, 15, 16, and 21-27 have been rejected under 35 U.S.C. § 102(b) as anticipated by the Novagen 1997 catalog. Applicant respectfully requests reconsideration and withdrawal of this rejection as it may be applied to the newly presented claims.

Applicant would first like to point out that this publication is not a prior art reference under 35 U.S.C. § 102(b) since the effective filing date of this application is July 15, 1997. In fact, it is not clear that this publication is prior art under any other paragraph of 35 U.S.C. § 102 since there is no indication in the material provided by the Examiner when this catalog became available to the public. Applicant respectfully requests that the Examiner provide Applicant with some evidence that the reference became publicly available prior to the effective filing date of the application.

In the interest of speeding the prosecution of this application, Applicant will assume for the sake of argument that the effective date of the reference is earlier than the effective filing date of the application. Applicant does not concede that this assumption is true and expressly reserves the right to rebut this assumption at a later time.

Claim 43 is the sole independent claim from which claims 44-62 depend. Claim 43

is drawn to a composition comprising DNA fragments of different lengths, wherein fragments of each length are present in an amount that produces bands of substantially equal intensity after the composition is separated by gel electrophoresis and stained with a detectable label.

A reference anticipates a claim "only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

*Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Even assuming that the Novagen catalog became publicly available prior to the effective filing date of this application, the reference does not anticipate the invention as presently claimed. In paragraph 16, page 7 of the Office Action, the Examiner pointed to the DNA markers on page 115 of the Novagen catalog as anticipating the present invention. As presently claimed, the compositions of the invention produce bands of substantially equal intensity after gel electrophoresis and staining with a detectable marker. On page 115 of the Novagen catalog provided by the Examiner there is a picture of a TAE agarose gel of the separation of the Novagen Markers. A comparison of the intensity of the 6 kb band to the intensity of the 1 kb band in the Novagen product indicates that they do not produce bands of substantially the same intensity. Accordingly, the Novagen catalog does not disclose a product that anticipates the presently claimed invention. Applicants respectfully request reconsideration and withdrawal of this rejection as it may be applied to the newly presented claims.

**VIII. *The Rejection of Claims 1-27, and 35-37 under 35 U.S.C. § 103(a) As Being Unpatentable Over the 1997 Novagen Catalog and the 1997 Invitrogen Catalog Must Be Withdrawn***

Claims 1-27, and 35-37 have been rejected under 35 U.S.C. §103(a) as being obvious

over the 1997 Novagen catalog in view of the 1997 Invitrogen catalog. Applicant respectfully requests reconsideration and withdrawal of this rejection as it may be applied to the newly presented claims.

The copy of the Invitrogen catalog provided by the Examiner with the Office Action was the 1998 version. As discussed above, the effective filing date of this application is July 15, 1997. Accordingly, this catalog is not prior art. In the interest of speeding the prosecution of this application, Applicant will assume for the sake of argument that the effective date of the reference is earlier than the effective filing date of the application. Applicant does not concede that this assumption is true and expressly reserves the right to rebut this assumption at a later time.

MPEP 2143.03 reads in pertinent part "[t]o establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." (*citing In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)). Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case for the obviousness of the presently claimed invention and respectfully request reconsideration and withdrawal of this rejection as it may be applied to the present claims.

As discussed above, the Novagen catalog does not disclose compositions that produce bands of substantially the same intensity when separated by gel electrophoresis and stained. The deficiencies of the Novagen catalog are not remedied by the Invitrogen catalog. The Invitrogen catalog was cited for the proposition that highlight bands were known in the art. The Invitrogen catalog does not disclose compositions having the characteristics of the presently claimed compositions. Since the prior art does not teach all the limitations of the invention as presently claimed, Applicants respectfully request reconsideration and

withdrawal of this rejection as it may be applied to the present claims.

### *Conclusion*

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicant(s) therefore respectfully request(s) that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicant(s) believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Robert W. Esmond  
Attorney for Applicant  
Registration No. 32,893

Date: May 9, 2002

1100 New York Avenue, N.W.  
Suite 600  
Washington, D.C. 20005-3934  
(202) 371-2600